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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1609	

NOTIFICATION DATE	DELIVERY MODE
09/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/820,627	SMITH ET AL.	
	Examiner	Art Unit	
	Caralynne Helm	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 20-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 20-37 is/are rejected.

7)☒ Claim(s) 23 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/269,999.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1 page.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference). For the sake of examination in light of the prior art, claim 21 was interpreted as having the addition of initiator and catalyst precede the polymerization of the 'foamed structure'

Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an embodiment where the addition of initiator and catalyst precedes the polymerization process, does not reasonably provide enablement for an embodiment where the initiator and catalyst are added after polymerization, as the claim is written. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to fully practice the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Ultimately eight factors were elucidated from these proceedings:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

All eight factors were considered in the analysis of enablement for the present invention.

The invention pertains to methods of making a porous structure of bonded particles with a predetermined level of porosity, pore size and interconnectivity. This method details a series of steps, with no specified order, that include the formation of a dispersion of particles to be bonded, liquid carrier and a polymerizable monomer, the addition of a surfactant followed by the

introduction of oxygen containing gas that is then agitated to form a foam, the polymerization of the foam, the addition of initiator and catalyst, the drying of the product and the firing of the product. As claimed, the invention stipulates that the polymerization of the monomeric material can occur in the absence of an initiator or catalyst. Although the claim states a desire to control the time between the formation of the foam and the start of polymerization, the breadth of the claim language includes embodiments where the monomeric material has the ability to self-initiate (e.g. steps c and d of claim 1 occur in the order written, where polymerizing of the foamed structure occurs before the addition of initiator and catalyst), thereby dramatically reducing if not eliminating the aspect of control. Consequently, a reasonable interpretation includes the onset of polymerization occurring at any point from when the monomers are placed in contact with one another, which would include times prior to or during the addition of surfactant, the introduction of oxygen containing gas, the agitation of the mixture as well as the addition of initiator and catalyst. Since the onset of polymerization would then be possible at a wide variety of times during the process, the predictability of the end product and control over its structure would no longer exist and the nature of the invention as producing a predetermined structure would be negated. In addition, the specification gives no guidance as to the nature of the invention when under the influence of a self-initiating monomer or the possible monomers that would be applicable to such an embodiment. Although the embodiment where the addition of the initiator and catalyst start the polymerization reaction is both enabled and exemplified in the specification, embodiments where the polymerization precedes the addition of the initiator and catalyst would require undue experimentation to make.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 24, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "easily" in claim 21 is a relative term, which renders the claim indefinite. The term "easily" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The ease at which bone cells adhere to a substrate is neither discussed nor quantified within the disclosure. Although the applicant does discuss the ability of bone tissue to grow into their invention as well as present pictorial data of the invention in a bone cell culture, no discussion or explanation is given to the level of difficulty or robustness of attachment of bone cells that may have infiltrated into the invention.

The applicant may act as his or her own lexicographer to specifically define a term of a claim and the written description must clearly define the claim term such that its meaning would be clear to one of ordinary skill in the art. Claim 21 uses the term "undersinter" to describe the process of firing that the applicant's claimed structure undergoes. "Undersinter" was not a term well known in the art at the time the invention was made. Thus, the term is indefinite because the specification does not clearly redefine the term.

The applicants use the phrase "consisting essentially of" in the method of claim 21. "The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52,190 USPQ 461, 463 (CCPA 1976) (emphasis in original)" (MPEP 2111.02) However claims 20, 36, and 37 set out additional steps that materially affect the basic and novel characteristics of the "porous article of bonded particles and having a predeterimined level of porosity pore size and interconnectivity" of claim

21. Thus the phrase "consisting essentially of" renders claim 21 indefinite as the specification does not give the phrase an alternate definition and presence of claims 20, 36 and 37 are contrary to its accepted meaning.

The phrase "less than about 5 micrometers" in claim 24 is a relative phrase, which renders the claim indefinite. The phrase " less than about 5 micrometers " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "less than" typically indicates a maximum point. However, the phrase "less than" is contraverted by the term "about" which implies that values above and below 5 micrometers are permitted. Further, the extent of variance permitted by "about" is unclear in the context. Therefore it is unclear whether "about 5 micrometers" simply includes 4 and 6 micrometers or if it could also include any value between 0 and 50 micrometers as well. Thus the interpretation of the phrase "less than" in this context is unclear as no definitive maximum can be defined.

The phrase "greater than about 150 micrometers" in claim 35 is a relative phrase, which renders the claim indefinite. The phrase "greater than about 150 micrometers" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "greater than" typically indicates a minimum point. However, the phrase "greater than" is contraverted by the term "about" which implies that values above and below 150 micrometers are permitted. Further, the extent of variance permitted by "about" is unclear in the context. Therefore it is unclear whether "about 150 micrometers" simply includes 149 and 151 micrometers or if it could also include any value between 100 and 200 micrometers as well. Thus the interpretation of the phrase "greater than" in this context is unclear as no definitive minimum can be defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-23, 25-32, and 34-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Tange et al. (US Patent No. 5,082,607) in light of Afeyan (US Patent No. 5,503,933), Lewis (Hawley's Condensed Chemical Dictionary), Ohtani et al. (US. Patent No. 5,278,250), Odian (Principles of Polymerization), Andrews (Electrophoresis Theory Techniques, and Biochemical and Clinical Applications), Van Vlack (Elements of Materials Science and Engineering), Ratner et al. (Biomaterials Science: An Introduction to Materials in Medicine) and Ellis (Porous Alumina Ceramics in Drug Delivery: Processing Concerns and Percolation Models). Here Lewis, Ohtani et al., Odian, Andrews and Van Vlack are relied upon to provide terminology definitions.

Tange et al. teach a method of preparation of a porous ceramic article in which a ceramic powder, a polymerizable compound, an emulsifying agent (e.g. a surfactant), and water are mixed together, polymerized, dried, and fired to produce the desired product (see abstract). More specifically, Tange et al. teach the creation of a dispersion with the ceramic material to be bonded, exemplified as alumina AES-11 (aluminum oxide) and zirconia (zirconium oxide) in described embodiments, monomers to be polymerized, a surfactant (sorbitan monostearate) and a dispersing agent (see examples 3 and 5). The ceramic solid material used by Tange et al. constitutes 40%-60% of the dispersion weight (see examples 3 and 4). The dispersion was gradually mixed with an aqueous solution of the initiator ammonium persulfate and vigorously stirred (see example 3). The mixing process by its very nature introduces air bubbles into the

mixture. Tange et al. go on to teach that the mixture is allowed to polymerize from 1 to 48 hours. This polymerization reaction undergone by the monomers, exemplified as styrene and methacrylate compounds, occurs by radical or redox polymerization (see abstract and examples 1 and 3). Tange et al. teach that the structure is subsequently dried and fired at a temperature of at least 1000°C (see column 5 lines 4-5, 21-22 and example 3). Tange et al. also teach the firing of their product at 1400°C for 2 hours, (see example 5). According to Tange et al. this firing process both removes the organic material and sinters ceramic particles to one another. The final product obtained by Tange et al. had an apparent porosity ranging from 27% to 84% and pore sizes ranging from 7 to tens of microns (see table 1 and column 8 lines 15-18). Tange et al. does not specifically disclose the size of the particles used in the process, the "undersintering" of the dried structure, or the true porosity of the resulting product. In addition, Tange et al. does not teach the use of catalyst, bone cells or drug in their process.

The applicant describes its firing process as "undersintering the formed article"; however, the definition of sintering according to Lewis in Hawley's Condensed Chemical Dictionary states that it is the agglomeration of metal or earthy powders at temperatures below the melting point (see instant claim 21). Thus undersintering is actually a process of sintering and the sintering process disclosed by Tange et al. meets that particular limitation of the instant claim.

Van Vlack teaches that apparent porosity gives a measure of the open pores in a ceramic where true (total) porosity gives a measure of the total pores (see page 299 example 9-1.2 and page 595 column 1 line 6). So in relating apparent to true porosity, the apparent porosity will be less then or equal to the true porosity. Since instant claim 32 claims the formed body as having true porosity from about 20% to about 95% and the variance of the term "about" is not defined, then the acceptable range could reasonable include any value between 0% and

100%. Therefore the true porosity values that correspond to the disclosed apparent porosity values taught by Tange et al. fall within the claimed range.

Ohtani et al. make use of alumina powder in the invention that describe (see column 7 line 49). In particular they teach the use of alumina AES-11 from the same chemical company as that used by Tange et al. (see Ohtani et al. column 7 lines 49-51 and Tange et al. column 5 lines 56-57). Ohtani et al. go on to teach further detail about the AES-11 material used, namely that its average particle size was 0.4μm (see column 7 lines 50-52). Thus, Tange et al. also teaches the use of particles "less than about 5 micrometers" in their dispersion, as claimed in instant claim 24. Tange et al. in light of Lewis, Van Vlack, and Ohtani et al. thereby teaches all the limitations of claims 21-35 except the use of a catalyst (where the low end of the 1-48 hour range taught by Tange et al. corresponds to "about 20 minutes" in claim 22, the 1400°C taught by Tange et al. corresponds to a firing temperature of "about 1250°C" and "about 1350°C" in claims 30 and 31 and "tens of microns" taught by Tange et al. corresponds to values within the range of "about 50 micrometers to about 150 micrometers" in claim 34 as well as "greater than about 150 micrometers" in claim 35).

Odian teaches that the term 'redox polymerization' is a descriptor used to describe radical polymerization reactions whose radical initiator forms due to an oxidation-reduction reaction (see page 219 section 3-4b). Regardless of the means by which the initiator is converted into radical form, the rate of polymerization is dependant upon the rate of initiation (see Odian page 208 equation 3-25). As previously discussed, Tange et al. teach that the polymerization reaction takes place from 1 to 48 hours, implying that the rate of reaction can vary. The particular initiator, ammonium persulfate, taught by Tange et al. is known in the art as one that forms oxygen free radicals in aqueous solution and that this process is catalyzed by the presence of base (see Andrews page 21 paragraph 3 lines 2-4). In addition, Afeyan et al. teach

that styrene and methacrylate compounds, the same classes of monomer compounds taught by Tange et al., can be polymerized by radical polymerization (see column 8 line 66 through column 9 line 7). In particular, Afeyan et al. go on to teach the use of ammonium persulfate and the basic catalyst TEMED (N,N,N,'N'-tetramethylethylenediamine) as the initiator-catalyst combination employed (see column 8 line 66 through column 9 line 7). Since the duration of the polymerization disclosed by Tange et al. has up to a 48-fold variation in duration, one of ordinary skill in the art at the time the invention was made would have found it obvious to exercise more control of the polymerization reaction time by adding a catalyst to the mixture. Therefore, the person of ordinary skill in the art would have found it obvious at the time the invention was made to modify the method of Tange et al. by adding a catalyst to the polymerization process. Thus, claims 21-35 are obvious over Tange et al. in light of Afeyan et al., Odian, Andrews, Lewis, Van Vlack, and Ohtani et al.

Ratner et al. teach the wide use of the ceramic alumina in biological applications due to its biocompatibility and positive wear attributes (see page 77 paragraph 1). Ratner et al. go on to discuss porous ceramics, in particular, and the ability of these structures to encourage the infiltration of bone cells and bone formation within its pores when they exceed 100 micrometers in size (see page 78 paragraph 2 lines10-12). Further teaching by Ratner et al. discusses a particularly good structure for such bone formation where the pore sizes range from 140 to 160 micrometers. In addition, Tange et al. teach that one of the products produced by their invention had a larger pore size than the others, its main distinction being the use of a dispersing agent; thereby, implying that the inclusion and choice of dispersing agent, in terms of type and quantity, may allow for the production of larger pore sizes (see example 3 and column 8 lines 16-18). The invention of Tange et al. specifically uses alumina as an exemplary ceramic material. In light of the teachings of Ratner et al., one skilled in the art at the time the invention

was made would have found it obvious to further modify the invention of Tange et al. to include the production of a product with pores in the range of 140 to 160 micrometers and grow bone within its pores (e.g. grow bone cells in the product). Therefore claims 21-36 are obvious over Tange et al. in light of Afeyan et al., Odian, Andrews, Lewis, Van Vlack, Ohtani et al., and Ratner et al.

Ellis teaches that porous ceramic matrices can be used for drug delivery (see page 50 paragraph 1 line 1). More specifically, Ellis teaches that the drug can be dispersed within the pores of the ceramic material and that the subsequent release behavior of the drug would depend upon the pore structure and drug solubility (see page 51 paragraph 1). In addition, Ellis also teaches the wide use of alumina as a ceramic biomaterial (see abstract). The invention of Tange et al. produces a porous alumina material and since these materials are known to be biocompatible, one of ordinary skill in the art at the time the invention was made would have found it obvious to further modify the invention of Tange et al. to include a drug in its pores. Therefore claims 20-37 are obvious over Tange et al. in light of Afeyan et al., Odian, Andrews, Lewis, Van Vlack, Ohtani et al., Ratner et al., and Ellis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21, 23-31 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-34 and 36-37 of U.S. Patent No. 5,563,106. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the instant application and patent '106 form a dispersion comprising a liquid carrier, particles to be bonded and a polymerizable monomer (see instant claim 21 and claim 29 of patent '106). Both also introduce gas into the dispersion, polymerize the monomeric material, and remove the liquid carrier to leave a solid article with pores derived for the bubbles of gas (see instant claim 21 and claim 29 of patent '106). Additionally, both inventions require particle sizes below 5 micrometers and introduce the gas to their mixtures by agitation (see instant claim 21 and claim 37 of patent '106). Although patent '106 does not specifically include the steps of adding a surfactant and firing of the resulting product, its open claim language can include these steps. Patent '106 also does not claim the addition of an initiator and catalyst, however the means by which the polymerization it does claim is performed is not specified. The use of an initiator and catalyst is a common way to polymerize monomers; therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a catalyst and initiator to polymerize the monomeric material on patent '106. Thus the inventions are indistinct for one another.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm
Examiner
Art Unit 1609

CH

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